

REMARKS

I. Amendment to the Claims:

Claims 38-42, 44-57, 89, 99, and 100 are pending and under examination in the instant application.

Claim 45 has been cancelled herewith without prejudice.

II. Withdrawal Of Prior Rejections:

Applicants gratefully acknowledge that the Examiner has withdrawn:

- (i) the objection to claims 46-48 and 100;
- (ii) the rejection of claims 38 and 89 under 35 U.S.C. § 112, second paragraph;
- (iii) the rejection of claim 57 under 35 U.S.C. § 112, first paragraph; and
- (iv) the rejection of claims 38-39, 42, 44-46, 48, 50-57, 89, and 99 under 35 U.S.C. § 103(a)

as allegedly being unpatentable over *Coy et al.* (U.S. Patent No. 5,073,624) in view of both *Fabris* (ref A55 in IDS of 8/11/04) and *Mocchegiani et al.* (ref A150 in IDS of 8/11/04). (*see*, Office Action, page 2).

III. Objections to the Claims:

The Office Action alleges that claim 45 is in improper dependent form for failing to further limit the subject matter of claim 44 (*see*, Office Action, pages 3-4).

Claim 45 has been cancelled herewith. Accordingly, Applicant respectfully submits that this objection has been rendered moot.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description:

Claims 38-42, 44-57, 89 and 99-100 were rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement (*see*, Office Action, pages 4-5). Specifically, the Office Action purports that claims 38 and 89 recite new matter because there is allegedly no support for measuring and comparing both the level of marker in

the patient's blood or serum and the level of newly produced T cells by monitoring TRECs. (see, Office Action, page 3).

Applicant respectfully traverses this rejection by responding to the three reasons outlined in the Office Action for this rejection.

First, the Office Action asserts that the "markers" recited at page 58, lines 1-3 of the application as filed relate only to markers found in blood or serum. As a preliminary matter, Applicant respectfully notes that TREC analysis is performed using the T cells isolated from the blood - in other words, it concerns "a marker found in blood or serum." It is further noted that the paragraph at page 58, lines 1-7, is not limited to the "known markers" described under section A. Although this paragraph is placed under section A, it is clear from its substance and context that it is not limited to only the "known markers" described in section A. This paragraph begins with the sentences: "Certain markers are associated with the activation of the thymus. By following the concentration of any one, *or any combination, of these markers*, one can monitor the level of the activation of the thymus." These opening sentences are directed to the "known markers" of section A (pages 58-63 of the application as filed), the "newly identified markers" of section B (pages 63-64 of the application as filed), and the "cellular markers" of section C (page 64 of the application as filed). That this is the correct understanding of the opening paragraph is made clear by looking at the second paragraph at page 58 which begins to address the "known markers" which are then described in greater detail. If the opening paragraph at page 58 were limited solely to "known markers" it would seem unnecessary for the application to specifically call them out in the second paragraph. Applicant further notes that there is also support for the combination of the markers as recited in the instant claims in original claim 38. For the Examiner's convenience, original claim 38 is provided below:

Original Claim 38. A method for determining the susceptibility of an at least partially atrophied thymus to reactivation in a patient, comprising:
monitoring the level in the patient's blood or serum **of one or more markers** associated with activation of the thymus,
disrupting sex steroid-mediated signaling to the thymus of the patient, monitoring the level in the patient's blood or serum **of the one or more markers**, and
comparing the level of the one or more markers before and after disruption of sex steroid-mediated signaling,
wherein an early increase in the level of any one of the markers following disruption of sex steroid-mediated signaling indicates susceptibility of the patient's thymus to reactivation. (emphasis supplied).

The plain language of the claim, which recites monitoring "of one or more markers associated with activation of the thymus," provides support for the instantly claimed method.

Second, the Office Action notes that the markers recited in section C are not functional equivalents of markers recited in section A. In response, Applicant is unclear as to why functional equivalency is required. The claims at issue recite the use of a first marker associated with the activation of the thymus and a second marker associated with the activation of the thymus (i.e., TRECs). One can determine the susceptibility of an at least partially atrophied thymus to reactivation in a patient by measuring these two markers. These two markers are adequately described and their combination is also suggested at page 58, lines 1-3 of the application as filed and original claim 38 (*see, above*).

Finally, the Office Action states that there is no single example wherein both the level of the marker in the patient's blood or serum, and the level of newly produced T cells by monitoring TRECs. Applicant notes that the Federal Circuit has made it explicitly clear that in accordance with its prior case law examples are not necessary to support the adequacy of a written description (*see, Falkner v Inglis*, 448 F.3d 1357 (Fed. Cir. 2006)). In *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.* the court held that "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." 424 F.3d 1336, 1345 (Fed. Cir. 2005).

Appl. No. 10/749,120
Atty. Docket No.: 286336.154US1/NOR-015CP2
Request for Continued Examination

In view of the foregoing, Applicant respectfully submits that the grounds for this rejection have been overcome. Accordingly, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

CONCLUSION

Upon entry of the instant amendment, claims 38-42, 44, 46-57, 89, 99, and 100 will remain pending in this application.

Applicants petition for a 1-month extension of time to respond to the outstanding Action. Please charge the fees for this 1-month extension and the RCE fees to our Deposit Account No. 08-0219. No additional fees are believed to be due in connection with this filing; however, if any fees are due, please charge such fees to our Deposit Account No. 08-0219.

If a telephone interview would advance prosecution of the application, the Examiner is encouraged to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: May 30, 2008

/Ann-Louise Kerner, Ph.D./
Ann-Louise Kerner, Ph.D.
Reg. No. 33,523

WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel.: (617) 526-6192
Fax: (617) 526-5000